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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,954	12/04/2001	Howard Jacobs	227-142	5957

7590 03/26/2003

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1100 North Glebe Road 8th Floor
Arlington, VA 22201-4714

EXAMINER

SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/26/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,954

Applicant(s)

JACOBS ET AL.

Examiner

Sally A Sakelaris

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10, drawn to methods of diagnoses and screening for a genetic predisposition by detecting the presence or absence of a mutation.

Group II, claims 11 and 12, drawn to a method of using a mutant form of the POLG gene as a diagnostic agent.

Group III, claim 13, drawn to a diagnostic kit containing reagents capable of indentifying the presence or absence of a mutation in the POLG gene.

Group IV, Claim 14, drawn to a method of using the POLG gene as an indicator of other pathological conditions.

2. The inventions listed as Groups I, II, III, and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

It is noted that each of the present claims has been presented in improper Markush format, as distinct methods are improperly joined in the claims. With respect to the methods of Groups I, II, and IV each one consists of analysis using a unique nucleic acid respectively, each differing in its structural and functional properties. Additionally, the method claims of Groups I, II and IV are distinct from the other in that both the mutation or mutations in the nucleic acids of

group I, the mutant form of Group II, and the POLG gene of group IV being analysed in the methods, comprise a distinct structure and as a whole each biomolecule is functionally distinct over each other. Additionally, the kit of Group III is different in composition and does not include the same process steps as those involved in the method groups. Each group has a different special technical feature. As the claimed methods and kit all use analysis with different polynucleotides, they do not share a special technical feature and the distinct methods and kit may not properly be presented in the alternative. Accordingly, the claims have been separated into a number of groups corresponding to the number of different inventions encompassed by the claims, and the claims will be searched only as they read upon the elected invention from the methods of Groups I, II, and IV and kit of Group III, require different analyses using different forms of polynucleotides.

Further, the claimed methods of Groups I, II, and IV have different objectives, require different process steps and require the use of different reagents. The method of Group I requires the steps of detecting the presence or absence of a mutation in a nucleic acid. The method of Group II requires the steps of using a mutant form encoding the catalytic subunit of mitochondrial DNA polymerase as a diagnostic agent or predictor. Group IV includes steps of using the POLG gene as an indicator for a variety of different pathological conditions. While Group I is directed to a method of detecting nucleic acids, group II uses mutant nucleic acids to diagnose male infertility while Group IV uses non-mutant forms to diagnose other pathological conditions.

The different nucleic acids require different method steps to accommodate their variant physical characteristics. In addition to differences in objectives, effects, and method steps, it is

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again noted that the method claims and the claim to a kit of the present Groups are not directed to the detection or identification of molecules having the same or common special technical feature, for the reasons discussed above.

3. Because these inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1, examination of these inventions lacking the same special technical feature would pose a serious burden on the examiner and therefore the lack of unity requirement and subsequent election of desired Group for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

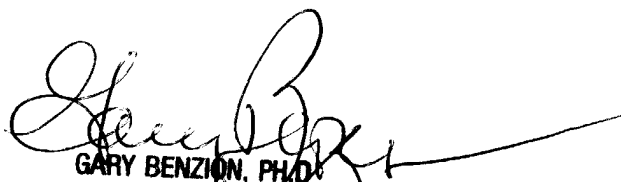
Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)308-1119. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris


3/20/2003


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
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